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Date: April 2, 1999

By: Christine C. Gurney  
Christine C. Gurney

PATENT  
Docket No. GC530-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UTILITY PATENT  
APPLICATION TRANSMITTAL LETTER



BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Enclosed for filing is the utility patent application of **Nathaniel T. Becker,**  
**Robert I. Christensen** and **Mark S. Gebert** for **MODIFIED STARCH COATING.**

Also enclosed are:

- ☐ \_\_\_ Sheets of [ ] formal [ ] informal Drawings
- ☒ Declaration and Power of Attorney, unexecuted
- ☐ Assignment
- ☐ Sequence Listing
- ☐ Computer Readable Sequence Listing, Diskette
- ☐ Statement of Sameness
- ☐ Information Disclosure Statement

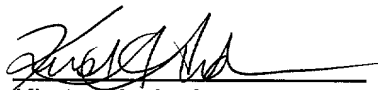
The filing fee has been calculated as shown below:

	No. of Claims	Extra Claims	Rate	Fee
Basic Application Fee				\$760.00
Total Claims	21	MINUS 20 = 1	X \$ 18	18.00
Independent Claims	2	MINUS 3 = 0	X \$ 78	-0-
If Multiple Dependent Claims are presented, add \$260				-0-
Add Recording Fee of \$40.00 if Assignment document enclosed				-0-
Total Application Fee Due				\$778.00

- ☒ Please charge \$778.00 to Deposit Account No. 07-1048 (Docket No. GC530-2). This paper is submitted in triplicate.

- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication, or credit any overpayment, to Deposit Account No. 07-1048 (Docket No. GC530-2). This paper is submitted in triplicate.
- ☒ Any additional fees required under 37 CFR 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application, or credit any overpayment, to Deposit Account No. 07-1048 (GC530-2). This paper is submitted in triplicate.
- ☒ Any patent application processing fees under 37 CFR 1.17.
- ☒ Any filing fees under 37 CFR 1.16 for presentation of extra claims.

Respectfully submitted,

  
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Date: April 2, 1999

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**PATENT**  
**Docket No. GC530-2**

**MODIFIED STARCH COATING**

**Inventors: Nathaniel T. Becker**  
**Robert I. Christensen, Jr.**  
**Mark S. Gebert**

**Related Applications**

This application is a continuation-in-part of U.S. Provisional Application No. 60/080,424, filed April 2, 1998, all of which is hereby incorporated herein in its entirety.

**Background of the Invention**

Coatings have long been used on seeds, pharmaceutical dosage forms, food or confectionery tablets, and granules such as enzymes granules to impart desirable characteristics to the final coated product. Developing coatings which have desirable properties is an ongoing source of research and development.

Thin film coating of pharmaceutical tablets allows efficient, controlled, uniform and reproducible coats. Use of multiple layers of coating, such as the polymeric undercoat, polymeric pigmented second coat and polymeric finish coat allows the preparation of very smooth glossy tablets (Ohno, U.S. Patent No. 4,001,390).

Numerous methods for pan-coating pharmaceutical tablets have been developed and are summarized in *Pharmaceutical Dosage Forms: Tablets*, Volume 3 (eds. Lieberman and Lachman, 1982, Marcel Dekker). They include sugar-coating techniques, solvent film coating, aqueous film coating, delayed release coating, and granule coating. Pulverized medicine may also be wrapped in a transparent, glossy, resistant, soluble or semi-permeable film as provided by Motoyama et al. (U.S. Patent No. 4,154,636).

Pharmaceutical tablets have been coated for a variety of reasons, including masking objectionable flavors or odors, protecting unstable tablet compositions,

providing protection of the tablet through the stomach with enteric coatings, improving the appearance of the tablet or separating medicine ingredients into a core segment and coating segment.

Aspirin tablets or other tablets that are powdery, easily dissolved and friable  
5 have been treated with a variety of coatings to keep them from dissolving too soon (John et al., U.S. Patent No. 4,302,440). Also, other polymers in non-aqueous vehicles have been used to granulate tablets (Gans et al., U.S. Patent No. 3,388,041) or to coat onto tablets (Jeffries, U.S. Patent No. 3,149,040) to protect from dissolving in the stomach or to delay the drug's release. Other non-aqueous  
10 film-coating systems have been designed to be applied to a variety of tablets containing a variety of active ingredients as illustrated by Singiser, U.S. Patent No. 3,256,111 and Brindamour, U.S. Patent No. 3,383,236. The aqueous coating processes are environmentally more safe than the non-aqueous processes, which involve the use of organic solvents in film-coating solutions. Thin film coatings,  
15 which do not alter the dissolution characteristics of the tablet, may be readily formed using aqueous film-coating processes. Unless adequately thick or insoluble coatings are used, most coatings are not capable of effectively masking the strong objectionable bitter taste of triprolidine hydrochloride or other compounds with similar properties.

20 Seed coating is a practice which has become widespread. It is aimed in particular at improving the germination characteristics, at providing various additives capable of intervening at any time during the growth of plants, at protecting the seeds or at imparting to the seed a shape of a size which is suitable for automatic sowing.

25 Granules such as enzyme-containing granules can also benefit from the presence of a coating. For example, it is desirable to coat enzyme granules in order to provide a cosmetic white or colored appearance, improve particle strength, reduce the tendency to dust in handling, reduce exposure of workers to enzymes and protect the enzyme against inactivation by moisture, oxidants and other harsh  
30 compounds. At the same time, it is important that such coatings not interact negatively with other detergent components. A coating material should also be easy to apply to the granule without excessive agglomeration or yield loss, typically by spraying onto the enzyme granules in a fluidized bed or tumbling coater.

### **Summary of the Invention**

The present invention provides a coating including a modified starch and a plasticizer. The modified starch is preferably hydroxypropyl modified starch. The plasticizer is preferably glycerol. The coating can further comprise a secondary  
5 polymer.

The present invention further provides a coating including a modified starch and a secondary polymer. The modified starch is preferably hydroxypropyl modified starch. The secondary polymer is preferably methyl cellulose. The coating can further comprise a plasticizer.

10 The present invention also provides a granule including a granule core and the coating of the present invention. Also provided are cleaning compositions, textile compositions and feed compositions including these granules.

The present invention additionally provides a composition including a tablet and the coating of the present invention, a coated pharmaceutical dosage form  
15 including a pharmaceutical dosage form and the coating of the present invention, a coated seed including a seed and and the coating of the present invention.

### **Detailed Description of the Invention**

A coating has been developed which provides the above desirable properties  
20 without any apparent negative interactions with detergent components. This coating consists of a modified starch in combination with a plasticizer and optionally a secondary polymer such as a modified cellulose. Another coating can be a modified starch in combination with a secondary polymer and optionally a plasticizer.

In general, unmodified starch or cellulose is not a good coating material. For  
25 example, generally, starch is not soluble unless gelatinized by cooking at elevated temperatures, and even then it is usually only partially soluble. Further, neither raw nor cooked starch is a good film former, nor is it easily plasticized. Unmodified cellulose is also insoluble in water.

Modified starch on its own is also not, in general, a good coating material  
30 and does not have all of the desired properties for a coating. However, it has been found that by adding a plasticizer such as glycerol, the combined modified starch/plasticizer not only has good solubility and barrier properties but is also a good coating material with excellent mechanical properties.

It has also been found that blends of modified starch and a secondary polymer such as modified cellulose have an advantage in that, for example, they combine the superior film-forming properties of modified cellulose, with the greater solubility and barrier properties of modified starch. The mechanical resilience of these films can be further improved by addition of plasticizers. A blend containing equal parts of each of these polymers, preferably with added plasticizers and pigments, has excellent film strength, good moisture barrier characteristics, and it is feasible to coat from a high solids (15-20% w/w) solution. Also, it is not tacky and can be coated onto, for example, granules or tablets without causing agglomeration.

Preferred starches have been modified in order to, for example, improve the solubility of the starch. Modified starches include starches that have been modified, for example, by acid thinning, debranching, cross-linking, instantizaton via jet cooking and spray drying or instantizaton via high temperature extrusion. Modifications to the starch include ethylation (ethyl group substitution), acetylation (acetyl group substitution), methylation (methyl group substitution), hydroxy-propyl substitution, hydroxy-ethyl substitution, carboxy-methyl substitution and hydroxypropyl methyl substitution. Examples of modified starches include:

	Pure Cote (B760 and B 790)	GPC
	Pure Set 765	GPC
	Potato starch T1 - T5	Western Polymer
	Amiogum 23	Cerestar (formerly American Maize)
	Amiogum 30	Cerestar (formerly American Maize)
	Amiogum 50	Cerestar (formerly American Maize)
25	Amerimaize 2217	Cerestar (formerly American Maize)
	Amerimaize 2300	Cerestar (formerly American Maize)
	Crisp Tex	Cerestar (formerly American Maize)
	Batter Tex	Cerestar (formerly American Maize)
	Amylean 1	Cerestar (formerly American Maize)
30	Ethylex gums (2015, 2035, 2040 and 2065)	AE Staley
	Mira-Gel	AE Staley
	Soft-Set	AE Staley
	Ultra-Set	National Starch
	Capsule starch	National Starch
35	Amylogum CLS	Avebe

Preferred modified starches are those that have hydroxypropyl substitutions. More preferably, the modified starch is Pure Cote.

Preferred plasticizers include fructose, high fructose corn syrup, glucose, lactose, maltose, galactose, raffinose/sucrose mixture, and other mono- and di-saccharide sugars, sugar alcohols such as glycerol and sorbitol, polyethylene glycols (MW 200-8000), nonionic surfactants such as linear alcohol ethoxylates and  
5 alkylphenol ethoxylates, polyols such as Neodol 23/6.5 and propylene glycol, maltodextrin, urea, triethylcitrate (TEC), citric acid, and other carboxylic acids or salts thereof.

Preferred secondary polymers include modified celluloses, polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP) and polyacrylamide. Modified celluloses include  
10 ethylcellulose, methylcellulose, propylcellulose, hydroxypropyl cellulose, cellulose esters and mixed esters such as: cellulose acetate, cellulose acetate butyrate (CAB), and cellulose acetate propionate (CAP).

The coating of the present invention may further comprise one or more of the following: extenders, lubricants, and pigments. Suitable pigments useful in the  
15 coating of the present invention include, but are not limited to, finely divided whiteners such as titanium dioxide or calcium carbonate or colored pigments and dyes or a combination thereof. Preferably such pigments are low residue pigments upon dissolution. Suitable extenders include sugars such as sucrose or starch hydrolysates such as maltodextrin and corn syrup solids, clays such as kaolin and  
20 bentonite and talc. Suitable lubricants include nonionic surfactants such as Neodol, tallow alcohols, fatty acids, fatty acid salts such as magnesium stearate and fatty acid esters, lecithin and waxes such as carnauba wax and beeswax.

The coating described herein may be applied by methods known to those skilled in the art of enzyme granulation, including pan-coating, fluid-bed coating,  
25 spray drying, or combinations of these techniques.

The coating of the present invention can be a final, outer coating or an inner layer such as in the case of a layered granule core.

The coating of the present invention can be used to coat, for example, pharmaceutical dosage forms, confectionery or food tablets, seeds, or granule cores  
30 to produce coated pharmaceutical dosage forms, confectionery or food tablets, seeds, or granules.

Pharmaceutical dosage forms that can be coated with the coating of the present invention include tablets, capsules, caplets and gellabs such as medicinal

tablets or vitamin tablets. A large number of pharmaceutical dosage forms that can be coated with the coating of the present invention are known to those of skill in the art. Some methods for coating pharmaceutical dosage forms are described in *Pharmaceutical Dosage Forms: Tablets*, Volume 3 (eds. Lieberman and Lachman, 1982, Marcel Dekker). Similar methods can be used to coat confectionery or food tablets such as non-pareils, chewing gum balls, pieces of candy and the like.

Methods for coating seeds are well known in the art such as those described in U.S. Patent 4,879,839.

Granule cores that can be coated with the coating of the present invention include those made according to the methods described in, for example, U.S. Patent 5,324,649; U.S. Patent Application Serial No. 09/215,095; U.S. Patent Application Serial No. 09/215,086; or U.S. Patent 4,740,469. The granule cores can be commercially available granules such as Purafect granules (Genencor International Inc., Rochester, NY) or Savinase granules (Novo Nordisk, Denmark).

The coated granule cores or granules can be used in, for example, cleaning compositions, compositions for use in treating textiles or for use in feed or food, e.g., baking.

The granules of the invention are useful in formulating various detergent compositions or personal care formulations such as shampoos or lotions. A number of known compounds are suitable surfactants useful in compositions comprising the granules of the invention. These include nonionic, anionic, cationic or zwitterionic detergents, as disclosed in US 4,404,128 to Barry J. Anderson and US 4,261,868 to Jiri Flora, et al. A suitable detergent formulation is that described in Example 7 of US Patent 5,204,015 (previously incorporated by reference). The art is familiar with the different formulations which can be used as cleaning compositions.

Granules of the invention can be included in known powdered and liquid detergents. The addition of the granules of the invention to conventional cleaning compositions does not create any special use limitation.

The present invention also relates to cleaning compositions containing the granules of the invention. The cleaning compositions may additionally contain additives which are commonly used in cleaning compositions. These can be selected from, but not limited to, bleaches, surfactants, builders, enzymes and bleach catalysts. It would be readily apparent to one of ordinary skill in the art what



additives are suitable for inclusion into the compositions. The list provided herein is by no means exhaustive and should be only taken as examples of suitable additives. It will also be readily apparent to one of ordinary skill in the art to only use those additives which are compatible with the enzymes and other components in the composition, for example, surfactant.

When present, the amount of additive present in the cleaning composition is from about 0.01% to about 99.9%, preferably about 1% to about 95%, more preferably about 1% to about 80%.

The granules of the present invention can be included in animal feed as a delivery vehicle for animal feed additives such as those described in, for example, US 5,612,055; US 5,314,692; and US 5,147,642.

One aspect of the invention is a composition for the treatment of a textile that includes granules of the present invention. For example, a cellulase can be incorporated in the granule and used in a process to treat denim as is well known in the art.

The following examples are representative and not intended to be limiting.

### Examples

#### Example 1

Seed: 25% of batch weight

Sucrose, sieved

Spray 1: Matrix layer: 41.33% of batch weight

1. Enzyme concentrate to achieve payload
2. Sucrose
3. Corn starch

Sucrose and corn starch were added directly to the UF concentrate at a 55% sucrose: 45% corn starch ratio. After calculating the amount of UF concentrate needed to achieve the desired payload, sucrose and corn starch were added to the matrix solution. The sucrose was added to the UF concentrate and mixed for 10 minutes. The corn starch was added next with moderately vigorous agitation. The corn starch was dispersed after 20-30 minutes. The matrix layer was sprayed on the sucrose seed in a fluidized bed granulator under the conditions noted in Table 1.

Spray 2: 20% of batch weight

$\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$

5 A 50% solution of the  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$  (1:1  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ :water) was sprayed on the granules above in a fluidized bed granulator under the conditions noted in Table 1.

Spray 3:

Coating: 3.67% of batch weight

- 10
1. 2.5% Methylcellulose A-15
  2. 2.5% Pure Cote B790
  3. 6%  $\text{TiO}_2$
  4. 1.0 Neodol
  5. 1.67% PEG 600

15 This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and  $\text{TiO}_2$  was added into the cold water. The Pure Cote and  $\text{TiO}_2$  was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and  $\text{TiO}_2$  has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the

20 temperature remained at 95°C, the methylcellulose (MC) A-15 was added. Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was

25 used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

**TABLE 1**

Running parameters:

	<b>Spray 1</b>	<b>Spray 2</b>	<b>Spray 3</b>	
START RATE	0.18	0.22	0.15	<b>Kg/min/nozzle</b>
END RATE	0.28	0.43	0.26	<b>Kg/min/nozzle</b>
RAMP TIME	90	30	60	<b>min.</b>
SPEC. GRAVITY	1.15	1.2	1.07	
BED TEMP	70	50	50	<b>°C</b>
ATOM. AIR PRES	5.3	3.9	5.3	<b>BAR</b>

- 5 In the following examples, materials and conditions for the seed, Spray 1 and Spray 2 are identical to those in Example 1. Conditions for Spray 3 are substantially the same as those shown in Table 1.

Example 2

10 Spray 3:

Coating: 14.17% of Batch Weight

1. 2.50% Methylcellulose A-15
2. 2.50% Pure Cote B790
3. 6.00% TiO<sub>2</sub>
- 15 4. 1.50% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO<sub>2</sub> was added into the cold water. The Pure Cote and TiO<sub>2</sub> was agitated for 10-15 minutes to aid in dispersion.

- 20 After the Pure Cote and TiO<sub>2</sub> has had time to disperse the temperature was brought

up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the methylcellulose (MC) A-15 was added.

Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The

- 5 PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

10 Example 3

Spray 3:

Coating: 13.67% of Batch Weight

1. 1.25% Methylcellulose A-15
2. 3.75% Pure Cote B790
- 15 3. 6.00% TiO<sub>2</sub>
4. 1.00% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO<sub>2</sub> was added into the cold water. The Pure Cote and TiO<sub>2</sub> was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO<sub>2</sub> has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the temperature remained at 95°C, the methylcellulose (MC) A-15 was added.

- 20 Generally, the MC disperses at a temperature above 60°C. After the 30 minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the MC A-15 dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this solution was used in the coater. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

30

Example 4:

Spray 3:

Coating: 13.67% of Batch Weight

1. 2.50% Hydroxypropylmethylcellulose E-15
- 5 2. 2.50% Pure Cote B790
3. 6.00% TiO<sub>2</sub>
4. 1.00% Neodol 2.3-65 T
5. 1.67% PEG 600

This outer coating was batched as an 18% dry solids solution. Cold water  
10 was added to a vessel, then the Pure Cote B790 and TiO<sub>2</sub> was added into the cold  
water. The Pure Cote and TiO<sub>2</sub> was agitated for 10-15 minutes to aid in dispersion.  
After the Pure Cote and TiO<sub>2</sub> has had time to disperse the temperature was brought  
up to 95°C. The temperature was kept at 95°C for 30 minutes. While the  
temperature remained at 95°C, the hydroxypropyl methylcellulose (HPMC) E-15 was  
15 added. Generally, the HPMC disperses at a temperature above 60°C. After the 30  
minutes at 95°C, the solution was cooled down to 20°C. At 30°C, the HPMC E-15  
dissolved. The PEG 600 and Neodol were added at this time. After 30 minutes, this  
solution was used in the coater. The coating was sprayed on the granules from  
Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed  
20 temperature was maintained at 20°C throughout the coater run.

Example 5

Spray 3:

Coating: 14.01% of Batch Weight

- 25 1. 6.16% Pure Cote B790
2. 1.56% Glycerol
3. 6.00% TiO<sub>2</sub>
4. 0.29% Sodium Laurel Sulfate

This outer coating was batched as an 30% dry solids solution. Cold water  
30 was added to a vessel, then the Pure Cote B790 and TiO<sub>2</sub> was added into the cold  
water. The Pure Cote and TiO<sub>2</sub> was agitated for 10-15 minutes to aid in dispersion.  
After the Pure Cote and TiO<sub>2</sub> has had time to disperse the temperature was brought  
up to 95°C. The temperature was kept at 95°C for 30 minutes. While the

temperature remained at 95°C, the glycerol and sodium laurel sulfate were added. After the 30 minutes at 95°C, the solution was cooled down to 20°C. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C

5 throughout the coater run.

#### Example 6

Spray 3:

Coating: 30% of Batch Weight

- 10    1. 14.94% Pure Cote B790  
      2. 4.20% Glycerol  
      3. 4.20% Carnauba Wax  
      4. 6.00% TiO<sub>2</sub>  
      5. 0.66% Sodium Laurel Sulfate

15            This outer coating was batched as an 30% dry solids solution. Cold water was added to a vessel, then the Pure Cote B790 and TiO<sub>2</sub> was added into the cold water. The Pure Cote and TiO<sub>2</sub> was agitated for 10-15 minutes to aid in dispersion. After the Pure Cote and TiO<sub>2</sub> has had time to disperse the temperature was brought up to 95°C. The temperature was kept at 95°C for 30 minutes. While the  
20    temperature remained at 95°C, the glycerol, carnauba wax and sodium laurel sulfate were added. After the 30 minutes at 95°C, the solution was cooled down to 20°C. The coating was sprayed on the granules from Spray 2 in a fluidized bed granulator under the conditions noted in Table 1. The bed temperature was maintained at 20°C throughout the coater run.

25

              Various other examples and modifications of the foregoing description and examples will be apparent to a person skilled in the art after reading the disclosure without departing from the spirit and scope of the invention, and it is intended that all such examples or modifications be included within the scope of the appended  
30    claims. All publications and patents referenced herein are hereby incorporated by reference in their entirety.

**What is Claimed Is:**

1. A coating comprising a modified starch and a plasticizer.
2. The coating of claim 1, wherein the coating further comprises a  
5 secondary polymer.
3. A coating comprising a modified starch and a secondary polymer.
4. A granule comprising a granule core and the coating of claim 1.  
10
5. The granule of claim 4, wherein the granule core comprises an  
enzyme.
6. A granule comprising a granule core and the coating of claim 3.  
15
7. The granule of claim 6, wherein the granule core comprises an  
enzyme.
8. A composition comprising a tablet and the coating of claim 1.  
20
9. A composition comprising a tablet and the coating of claim 3.
10. A cleaning composition comprising the granule of claim 4.
- 25 11. A cleaning composition comprising the granule of claim 6.
12. The coating of claim 1, wherein the modified starch is a hydroxypropyl  
modified starch.
- 30 13. The coating of claim 3, wherein the modified starch is a hydroxypropyl  
modified starch.

14. A coated pharmaceutical dosage form comprising a pharmaceutical dosage form and the coating of claim 1.

5 15. A coated pharmaceutical dosage form comprising a pharmaceutical dosage form and the coating of claim 3.

16. A coated seed comprising a seed and the coating of claim 1.

17. A coated seed comprising a seed and the coating of claim 3.

10

18. A textile composition comprising the granule of claim 4.

19. A textile composition comprising the granule of claim 6.

15

20. A feed composition comprising the granule of claim 4.

21. A feed composition comprising the granule of claim 6.



**Abstract**

Coatings for pharmaceutical dosage forms, food and confectionery tablets, seeds and granule cores are described. The coating includes a modified starch and a plasticizer optionally in combination with a secondary polymer. Also described is a  
5 coating including a modified starch and a secondary polymer optionally in combination with a plasticizer. Also described are coated pharmaceutical dosage forms, food and confectionery tablets, seeds and granule cores. Further described are cleaning, textile and feed compositions including the coated granule cores.

DECLARATION  
AND POWER OF ATTORNEY

ORIGINAL APPLICATION

AS A BELOW NAMED INVENTOR, I HEREBY DECLARE THAT:

MY RESIDENCE, POST OFFICE ADDRESS AND CITIZENSHIP ARE AS STATED BELOW NEXT TO MY NAME. I BELIEVE I AM THE ORIGINAL, FIRST AND SOLE INVENTOR (IF ONLY ONE NAME IS LISTED BELOW) OR AN ORIGINAL, FIRST AND JOINT INVENTOR (IF PLURAL NAMES ARE LISTED BELOW) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION ENTITLED **MODIFIED STARCH COATING**, THE SPECIFICATION OF WHICH

CHECK ONE:

☒ IS ATTACHED HERETO

☐ WAS FILED ON \_\_\_\_\_ AS APPLICATION SERIAL NO. \_\_\_\_\_.

I HEREBY STATE THAT I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE. I ACKNOWLEDGE THE DUTY TO DISCLOSE INFORMATION WHICH IS MATERIAL TO PATENTABILITY AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS §1.56.

I HEREBY CLAIM FOREIGN PRIORITY BENEFITS UNDER TITLE 35, UNITED STATES CODE §119, OF ANY FOREIGN APPLICATION(S) FOR PATENT OR INVENTOR'S CERTIFICATE LISTED BELOW AND HAVE ALSO IDENTIFIED BELOW ANY FOREIGN APPLICATION FOR PATENT OR INVENTOR'S CERTIFICATE HAVING A FILING DATE BEFORE THAT OF THE APPLICATION ON WHICH PRIORITY IS CLAIMED.

APPLICATION NUMBER	COUNTRY	DATE OF FILING	PRIORITY CLAIMED	
			YES	NO

I HEREBY CLAIM THE BENEFIT UNDER TITLE 35, UNITED STATES CODE §120, OF ANY UNITED STATES APPLICATION(S) LISTED BELOW AND, INsofar AS THE SUBJECT MATTER OF EACH OF THE CLAIMS OF THIS APPLICATION IS NOT DISCLOSED IN THE PRIOR UNITED STATES APPLICATION IN THE MANNER PROVIDED BY THE FIRST PARAGRAPH OF TITLE 35, UNITED STATES CODE §112, I ACKNOWLEDGE THE DUTY TO DISCLOSE MATERIAL INFORMATION AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS §1.56(A) WHICH OCCURRED BETWEEN THE FILING DATE OF THE PRIOR APPLICATION AND THE NATIONAL OR PCT INTERNATIONAL FILING DATE OF THIS APPLICATION.

APPLICATION NUMBER	DATE OF FILING	STATUS - PATENTED, PENDING OR ABANDONED
60/080,424	APRIL 2, 1998	PENDING

**POWER OF ATTORNEY:** AS A NAMED INVENTOR I HEREBY APPOINT AS MY ATTORNEY(S) WITH FULL POWER OF SUBSTITUTION AND REVOCATION, TO PROSECUTE THIS APPLICATION AND TRANSACT ALL BUSINESS IN THE PATENT AND TRADEMARK OFFICE CONNECTED THEREWITH:

MARGARET A. HORN, REG. No. 33,401  
CHRISTOPHER L. STONE, REG. No. 35,696  
KIRSTEN A. ANDERSON, REG. No. 38,813  
DEBRA J. GLAISTER, REG. No. 33,888

SEND CORRESPONDENCE TO:

KIRSTEN A. ANDERSON  
GENENCOR INTERNATIONAL, INC.  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304-1013

DIRECT TELEPHONE CALLS TO:

(650) 846-7676

**201**

FULL NAME OF INVENTOR	FULL FIRST NAME NATHANIEL	INITIAL T.	LAST NAME BECKER	
RESIDENCE & CITIZENSHIP	CITY BURLINGAME	STATE OR FOREIGN COUNTRY CALIFORNIA		COUNTRY OF CITIZENSHIP US
POST OFFICE ADDRESS	POST OFFICE ADDRESS 2116 HILLSIDE DRIVE	CITY BURLINGAME	STATE OR COUNTRY CALIFORNIA	ZIP CODE 94010

**202**

FULL NAME OF INVENTOR	FULL FIRST NAME CHRISTENSEN, JR.	INITIAL I.	LAST NAME ROBERT	
RESIDENCE & CITIZENSHIP	CITY PINOLE	STATE OR FOREIGN COUNTRY CALIFORNIA		COUNTRY OF CITIZENSHIP US
POST OFFICE ADDRESS	POST OFFICE ADDRESS 2156 BLUE JAY CIRCLE	CITY PINOLE	STATE OR COUNTRY CALIFORNIA	ZIP CODE 94564

**203**

FULL NAME OF INVENTOR	FULL FIRST NAME GEBERT	INITIAL S.	LAST NAME MARK	
RESIDENCE & CITIZENSHIP	CITY SOUTH SAN FRANCISCO	STATE OR FOREIGN COUNTRY CALIFORNIA		COUNTRY OF CITIZENSHIP US
POST OFFICE ADDRESS	POST OFFICE ADDRESS 500 MAPLE AVENUE, #9	CITY SOUTH SAN FRANCISCO	STATE OR COUNTRY CALIFORNIA	ZIP CODE 94080

I FURTHER DECLARE THAT ALL STATEMENTS MADE HEREIN OF MY OWN KNOWLEDGE ARE TRUE AND THAT ALL STATEMENTS MADE ON INFORMATION AND BELIEF ARE BELIEVED TO BE TRUE; AND FURTHER THAT THESE STATEMENTS WERE MADE WITH THE KNOWLEDGE THAT WILLFUL FALSE STATEMENTS AND THE LIKE SO MADE ARE PUNISHABLE BY FINE OR IMPRISONMENT, OR BOTH, UNDER SECTION 1001 OF TITLE 18 OF THE UNITED STATES CODE , AND THAT SUCH WILLFUL FALSE STATEMENTS MAY JEOPARDIZE THE VALIDITY OF THE APPLICATION OR ANY PATENT ISSUING THEREON.

SIGNATURE OF INVENTOR <b>201</b>	SIGNATURE OF INVENTOR <b>202</b>
DATE	DATE
SIGNATURE OF INVENTOR <b>203</b>	
DATE	